5.0 Premarket Notification (510(k)) Summary

Sponsor Information:

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

JUL 15 2009

Contact Person: Jizhong Jin
Senior Regulatory Affairs Associate
Phone Number: (651) 733-6655
FAX Number: (651) 737-5320

Date of Summary: December 22, 2008

Device Name and Classification:

Common or Usual Name: Electronic Stethoscope

Proprietary Name: 3M™ Littmann® Electronic Stethoscope Model 3200

Classification Name: Electronic Stethoscope (21 CFR § 870.1875(b))

Performance Standards: None

Predicate Device:

3M™ Littmann® Electronic Stethoscope, Model 3000
3M™ Littmann® Electronic Stethoscope, Model 4100

Description of Device:

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is a healthcare device that picks up sounds of the heart, arteries, veins, lungs and other internal organs with the use of selective frequency ranges. After amplification and filtering, the sounds are transferred to the user's ears via an active speaker and passive sound tubes.

The Model 3200 can also exchange audio data with a personal computing device (PC) using wireless Bluetooth link.

The user interface includes a 5-button keypad and an LCD display. Sound processing is carried out with the aid of a digital signal processor.
The Model 3200 does not incorporate any off-the-shelf (OTS) software.
The Model 3200 operates on one (1) AA alkaline, lithium, or NiMH battery.

Indications for Use:

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

Comparative Data for Determining Substantial Equivalence of New Device to Predicate Device:

Information provided in this 510(k) submission shows that 3M™ Littmann® Electronic Stethoscope, Model 3200 is substantially equivalent to the predicate device 3M™ Littmann® Electronic Stethoscope, Model 3000, cleared under K050159 and Littmann® Electronic Stethoscope, Model 4100, cleared under K051790 in terms of intended use, indications for use, composition, physical properties and technological characteristics. There are no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2009

3M Health Care
c/o Mr. Jizhong Jin
Regulatory Affairs
3M Infection Prevention Division
3M Center, Bldg 275-05-W-06
St. Paul, MN 55144-1000

Re: K083903
Trade/Device Name: 3M™ Littmann® Electronic Stethoscope, Model 3200
Regulatory Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope
Regulatory Class: Class II (Two)
Product Code: DQD
Dated: June 16, 2009
Received: June 17, 2009

Dear Mr. Jin:

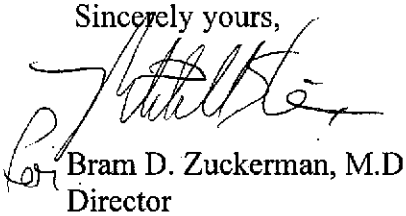
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083903

Device Name: 3M™ Littmann® Electronic Stethoscope Model 3200

Indications For Use: The 3M™ Littmann® Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Zack Kerman

(Division Sign-Off) 7/15/09

Division of Cardiovascular Devices

510(k) Number K083903